UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,266	03/16/2004	Shane Atwell	022132-000910US	4749

20350 7590 04/04/2006

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
STEADMAN, DAVID J	
ART UNIT	**PAPER NUMBER**
1656	

DATE MAILED: 04/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,266	ATWELL ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 1-40 are pending in the application.

[3] Applicant's preliminary amendment to the specification, filed on 8/16/2004, is acknowledged.

[4] Receipt of a sequence listing in computer readable form (CRF), a paper copy thereof, a statement of their sameness, a statement that no new matter has been added to the specification by the paper copy of the sequence CRF, and an amendment directing entry of said sequence listing into the specification, all filed on 8/16/2004, is acknowledged.

[5] Receipt of a Declaration, filed on 2/4/2005, is acknowledged.

[6] It is noted that claims 36-37 are drawn to "[t]he method of claim 35." However, claim 35 is drawn to a purified protein, not a method. For purposes of grouping claims 36-37, the claims have been interpreted as being drawn to the protein of claim 35.

Election/Restriction

[7] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 33, and 35-37, drawn to a purified or crystallizable EGFR or EGFRKD and a crystal thereof, classified in class 435, subclass 194.

II. Claims 39-40, drawn to an insect cell capable of expressing EPHA7, classified in class 435, subclass 348.

III. Claims 6-8, drawn to a method of identifying a ligand that binds EPHA7, classified in class 436, subclass 4.

IV. Claims 9-17, drawn to a machine-readable medium, a computer readable database comprising the 3-D structural coordinates of a EPHA7KD binding pocket, and a method for producing same, classified in class 345, subclass 419.

V. Claims 18, 20, 30, and 32, drawn to a computer readable database comprising a representation of a compound capable of binding a EPHA7KD binding pocket, and a method for producing same, classified in class 345, subclass 419.

VI. Claim 19, drawn to a method for producing a computer readable database comprising a representation of a EPHA7KD binding pocket in a co-crystal with a compound, classified in class 345, subclass 419.

VII. Claims 21 and 23, drawn to methods of modulating EPHA7KD activity, classified in class 514, subclass 789.

VIII. Claim 22, drawn to a method of producing a compound, classified in class 514, subclass 789.

IX. Claim 24, drawn to a method of identifying an activator or inhibitor, classified in class 435, subclass 15.

X. Claim 25, drawn to a method for homology modeling, classified in class 702, subclass 27.

XI. Claims 26-28 and 31, drawn to a method for identifying or designing a compound that binds EPHA7KD or a method for determining whether a compound binds EPHA7KD, classified in class 702, subclass 19.

XII. Claim 29, drawn to a method of producing a mutant EPHA7KD having an altered property, classified in class 435, subclass 440.

XIII. Claims 34 and 38, drawn to methods of purifying EPHA7 protein, classified in class 530, subclass 412.

[8] The inventions are distinct, each from the other because:

[9] The computer readable databases of Groups III and IV are distinct as they each comprise structural coordinates of distinct entities and the database of Group III would not render the database of Group IV obvious to one of ordinary skill in the art and vice versa.

[10] The polypeptide of group I, the insect cell of Group II and the databases of groups IV-V are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and the polynucleotide of the insect cell, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group II does not necessarily encode a polypeptide

of group I. Furthermore, the information provided by the polynucleotide of group II can be used to make a materially different polypeptide than that of group I. For example, the nucleic acid of the insect cell, because of a frameshift, can result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with an EGFR. In addition, while a polypeptide of group I can made by methods using some, but not all, of the polynucleotides that fall within the scope of group II, it can also be recovered from a natural source using biochemical means or can be made by purely synthetic means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of groups I and II together.

[11] The inventions of groups I-II are unrelated to the databases of Groups IV-V as they comprise unrelated entities that are capable of separate manufacture, use, and effect.

[12] The protein of Group I is related to the methods of Groups III, VI, VII, IX, XI, and XIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the protein of Group I can be used as an antigen in the production of an antibody.

[13] The protein of Group I is unrelated to the method(s) of Group(s) VIII, X, and XII as it is neither made nor used by the methods of Groups VIII, X, and XII.

[14] The insect cell of Group II is unrelated to the method(s) of Group(s) III and VI-XII as it is neither made nor used by the methods of Groups III and VI-XII.

[15] The insect cell of Group II is related to the method of Group XIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the insect cell of Group II can be used for producing a protein other than the protein of Group I or alternatively, the method of Group XIII can be practiced using

EPHA7 protein expressed from a cell other than the insect cell of Group II, *e.g.*, EPHA7 expressed from a mammalian cell.

[16] The machine readable media of Groups IV-V are unrelated to the method(s) of Group(s) III, VII-X, and XIII as it is neither made nor used by the methods of Groups III, VII-X, and XIII.

[17] The machine readable media of Groups IV-V are related to the methods of Groups VI, XI, and XII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the machine-readable media of Groups IV-V can be used to store data other than structural coordinates, such as a music composition or a literary work.

[18] The methods of Groups III and VI-XIII are distinct as they utilize different products, comprise different method steps, and/or yield different results.

[19] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-XIII are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search.

Each of the inventions requires a separate patent and non-patent literature search requiring a different text search for each Group and thus, co-examination of the inventions of Groups I-XIII would require a serious burden on the examiner.

[20] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[21] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

[22] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656